## REMARKS

Upon entry of this amendment, claims 1, 3-7 and 12-23 will be pending. Claim 2 has been cancelled. Claims 1, 3 and 4 have been amended. Support for the amendments to the claim 1 is found in the specification and claims as originally filed. For example, support is found at page 7, lines 15-16. Claims 3 and 4 have been amended to clarify that the magnesium stearate is present in an amount of from 0.5 to 2% by weight. No new matter is added.

**Rejections under 35 USC § 103(a)**

Claims 1-7, 12, 14, and 22 are rejected as unpatentable over WO/2001/078963 ("Staniforth"). Claim 2 has been cancelled, rendering the rejection moot as applied to that claim. The rejection is traversed as applied to the remaining claims as amended.

Claim 1, the sole independent claim, is directed to a dry powder formulation for inhalation. The amended claim specifies that the dry powder formulation comprises active particles, carrier particles, and magnesium stearate in an amount of at least 0.5% by weight of the formulation, wherein the particles of magnesium stearate are disposed on the surface of the carrier particles, and wherein the coverage of the magnesium stearate on the surface of the carrier particles is less than 5%.

Staniforth is relied upon for its description of a powder formulation for use in a multidose dry powder inhaler, the formulation comprising an active agent, carrier particles, and magnesium stearate in an amount from 0.02% to 1.5% by weight of the formulation. Office action at p. 3, last para. Staniforth is further relied upon for describing a surface coverage of the carrier particles that is "at least 5%". Office action at p. 4, first para. Staniforth does not describe or suggest a formulation comprising carrier particles wherein the coverage of the magnesium stearate on the surface of the carrier particles *is less than 5%*, as required by amended claim 1.

Moreover, Staniforth explicitly states that the carrier particles of the formulation should have coverage of *at least 5% and preferably 15%*. Staniforth at p. 11, lines 3-8. This is in agreement with the understanding in the art, at the time of the invention, that higher coverage with less calcium stearate was optimal. This is evidenced by WO 2000/53157 by Chiesi Pharmaceuticals ("Chiesi") (included with this response). Chiesi is referred to by Staniforth for

its description of magnesium stearate particles partially coating the surface of carrier particles. *See* Staniforth at p. 6, lines 19-23. Chiesi teaches that it is desirable to coat as much of the surface of the carrier particles as possible using a small amount of a "lubricant", which is preferably calcium stearate. Chiesi at p. 5 lines 6-9 and p. 6 lines 20-22. Specifically, Chiesi teaches that the coating should be *more than 10%* and preferably *more than 35%*. Chiesi at p. 6, lines 5-12.

In contrast to these descriptions in the prior art indicating that *higher* coverage of the carrier particles with calcium stearate was desirable, Applicant's specification teaches that "[t]he formulations of the present invention are prepared in a manner *to ensure the lowest possible coverage* of magnesium stearate on the carrier particles." Specification at p. 7, lines 25-26. This is based upon Applicants' surprising discovery that the effect of surface coverage on the performance of the dry powders is minor compared to the moisture protection and lubricating properties of the magnesium stearate. Specification at p. 5, lines 4-8. Accordingly, if the surface coverage of the carrier particles by magnesium stearate is kept low, it is possible to employ relatively large amounts of magnesium stearate and still obtain a reproducibly high fine particle fraction. Specification at p. 5, lines 8-12. Thus, absent the teachings of Applicants' specification, the skilled person would have sought to *increase* the coverage of magnesium stearate on the carrier particles and would have had no reason to produce a dry powder formulation wherein the coverage of the magnesium stearate on the surface of the carrier particles *is less than 5%*, as required by amended claim 10.

In summary, a dry powder formulation wherein the coverage of the magnesium stearate on the surface of the carrier particles *is less than 5%* is neither disclosed nor suggested by Staniforth. Accordingly, a *prima facie* case of obviousness has not been established with respect to claim 1, or its dependent claims. Reconsideration and withdrawal of the rejection is requested.

Claims 13, 15-21, and 23 are rejected over Staniforth in combination with U.S. Patent No. 6,645,466 ("Keller"). Applicants traverse. Claims 13, 15-21, and 23 each depend from claim 1 and Keller does not overcome the deficiencies of Staniforth discussed above with respect to claim 1. Accordingly, a *prima facie* case has not been established with respect to these claims, which contain all of the limitations of claim 1. Reconsideration and withdrawal of the rejection is requested.

**Double Patenting Rejection**

Claims 1-7 and 12-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 10 and 24-42 of copending application U.S. Serial No. 12/536,980 in view of Staniforth.

Since the rejection is provisional, Applicants defer addressing the rejection until such time as one or more of the conflicting claims is deemed allowable. Applicants request a Notice of Allowance.

A Supplemental Information Disclosure Statement and Petition for extension of time accompany this response along with the appropriate fees. Please charge any additional fees that may be due, or credit any overpayment, to Deposit Account No. 50-0311, Attorney Reference No. 28069-625N01US.

Respectfully submitted,

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